SEP 26 2007

510(k) Summary – K071998

In accordance with 21 CFR 807.87(h), the following 510(k) summary has been prepared per 21 CFR 807.92.

Echogenic Introducer Needle 510(k) Summary

Submitter:	ARROW International, Inc. 2400 Bernville Road Reading, PA 19605-9607 USA
Contact person:	Kirsten Stowell Regulatory Affairs Specialist Phone: 610-378-0131, ext. 3514 Fax: 610-478-3128 Email: kirsten.stowell@arrowintl.com
Date summary prepared:	August 30, 2007
Device trade name:	Arrow Echogenic Introducer Needle
Device common name:	Introducer Needle
Device classification:	Hypodermic single lumen needle; Product Code FMI; 21 CFR 880.5570, Class II
Legally marketed devices to which the device is substantially equivalent:	Arrow Echogenic Needle (K040100, SE date 3/1/2004) Arrow Extended Vascular Access Needle (K924338, SE date 3/18/1993) Radial Artery Catheterization Set with integral needle protection (K021120, SE date: 5/2/2002) PICC Two-Lumen Peripherally Inserted Central Catheter Kit with Blue FlexTip® Catheter and Integral Needle Protection (K003006, SE date: 10/27/2000)
Description of the device:	The Arrow Echogenic Introducer Needle has the following characteristics: • Outside Diameter = 18Ga – 21Ga • Inside Diameter = 0.0240 – 0.042 in. • Usable lengths of 1 ½ - 2 ¾ in. (3.81 - 7cm) • Grit-blast echogenic surface treatment
Intended use of the device:	The intended use is the same as the predicate devices.
Indications for use:	The Indication for Use is the same as the predicate device.

Technological characteristics:	The proposed echogenic introducer needle has the same technological design characteristics as the predicate echogenic introducer needle devices. This design includes the same needle lubricant as the predicate introducer needles with integral needle protection.
Performance tests:	The following tests were performed to demonstrate substantial equivalence: • Needle penetration test • Hub bond tensile strength test
Assessment of non-clinical performance data:	The results of the bench tests demonstrate that Arrow's echogenic introducer needle is as safe and effective as compared to the currently marketed predicate introducer needle.
Summary	Arrow International's echogenic introducer needle has the same intended use as the predicate devices. Based on the assessment of non-clinical performance data to verify the intended use, and the technological characteristic comparison, Arrow's echogenic introducer needle is substantially equivalent to the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Kirsten Stowell
Regulatory Affairs Specialist
ARROW International, Incorporated
2400 Bernville Road
Reading, Pennsylvania 19605-9607

SEP 26 2007

Re: K071998
Trade/Device Name: Arrow Echogenic Introducer Needle Component
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: August 28, 2007
Received: August 29, 2007

Dear Ms. Stowell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known):

Device Name: Arrow Echogenic Introducer Needle Component

The Arrow Echogenic Introducer Needle allows access to the vascular system for the introduction of a guidewire to facilitate catheter placement.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K971998